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Application No. 09/922,418

REMARKS

Claims 1, 13, 18, 50, 62, 67, 89, 89, 90, 136, 149, 153 and 165 are hereby amended and after entry of this response claims 1-98 and 133-168 remain pending in the present application. Applicant respectfully requests reconsideration by the Examiner in light of the following remarks.

First, the Applicant would like to thank the Examiner for extending the courtesy of an interview with Dr. David Masters and the undersigned, as representatives of the Applicant, on September 26, 2005, to discuss the above identified application and the reconsideration of the pending claims thereof. The Applicant acknowledges the content of the interview summary (Form PTOL-413) prepared by the Examiner, dated September 26, 2005. Furthermore, the following remarks include the issues addressed in the interview and may be considered a summary of the interview as well as a reply to the Office Action.

The Examiner has rejected claims 50-52, 54, 55 and 63-66 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,800,792 (McKnight et al). The Examiner has asserted that McKnight teaches "a collagen film dressing impregnated with finely divided silver...Glutaraldehyde is disclosed as a tanning agent...Water is specified... and Compression is disclosed". However, even though McKnight discloses a collagen film dressing including silver, glutaraldehyde, and water, the Applicant respectfully states that the reference cited by the Examiner does not disclose or suggest an electromatrix device wherein the protein materials, conductive materials, pharmacologically active agents and biocompatible solvents are formed into a non-brittle cohesive body and compressed. Therefore, the present claims provide claim limitations that are not present in McKnight. For example, claim 50 (and the related dependent

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Application No. 09/922,418

claims) claims an electromatrix device that is formed by compressing a non-brittle cohesive body to remove bulk biocompatible solvent and generate additional interactive forces.

As previously mentioned, the solvated protein matrix material of the present invention is formed by compressing a non-brittle cohesive body. A cohesive body, as disclosed in the present application, is formed when a composition, including the protein materials and biocompatible solvents, includes the proper proportions of the protein and solvent to make such a protein/solvent composition cohesive (i.e. the composition prefers to stick to itself rather than other materials) and formable (e.g. may be formed into a desired shape or configuration). See the present application at pages 16 and 17. Additionally, the compression of such a non-brittle cohesive body of the present invention has been found to produce a material that possesses enhanced strength, durability, and pliability over other types of materials including similar components, such as gelatin and/or crosslinked matrices. Moreover, it has generally been found that an excessively dried protein material, gelatin and/or crosslinked matrix will tend to crack, shatter, break or otherwise lack cohesiveness (i.e. have brittle characteristics), because such materials already have a fixed structure.

Additionally, as previously suggested, the cohesive body is generally *non-brittle*. This non-brittle nature of the cohesive body, which allows mobility of its components within, permits the removal of bulk water and the forming of additional interactive forces upon compression. See page 6, lines 10-18, page 8, lines 22-23, page 9 lines 1-2 and pages 13-15. Contrary to the non-brittle cohesive body of the present invention, it is well known in the art that as a protein material is excessively dried, gelled and/or crosslinked (e.g. gelatins or cross-linked matrices), the protein molecules become more ordered and fixed into position due to both physical and chemical bonds among the proteins. These bonds render such protein materials

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Application No. 09/922,418

brittle (i.e. likely to break, snap or crack, as when subjected to pressure; as generally defined in many dictionaries) and also inhibits the mobility of the components within the material upon compression. This inhibits the removal of bulk water and the formation of additional interactive forces upon compression. The ability of the proteins to continue to change conformation and re-organize is lost or unacceptably diminished by such bonds when the protein materials are excessively dried, gelled and/or crosslinked. The formation of a brittle material is generally expected when the McKnight collagen fiber dispersion is gelled and subsequently crosslinked before compression. Therefore, the gelling and/or crosslinking of the McKnight solvent composition inhibits the protein and solvent composition from forming a non-brittle cohesive body.

It is also noted that some materials, such as gelatin or crosslinked matrices, even though flexible in some embodiments, are generally still considered brittle. This is due to the strong physical and chemical bonds created during the formation of such materials. For example, gelatins, such as Jello®, are very flexible, but still brittle. This is evident in that Jello® can be broken or separated under pressure or flexion and once broken is not cohesive unto itself as to allow for it to be molded or pressed together to thereby repair or restore the gelatin to its original state. Again, it is noted that the cohesive body of the present invention is capable of such restoration since it is cohesive (i.e. prefers to stick to itself rather than other materials). Moreover, gelatin is generally defined as "a *brittle*, nearly transparent, faintly yellow, and almost tasteless glutinous substance...". See Webster's New Universal Unabridged Dictionary published by Barnes and Noble, Inc. 1994. It is again noted that materials that are excessively dried, gelled and/or crosslinked, such as Jello® or the gelled and crosslinked material of McKnight, cannot

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form the non-brittle cohesive body and ultimately cannot form the solvated protein matrix material and/or devices of the present invention.

McKnight discloses a collagen fiber dispersion that is gelled, spread into a film, tanned (i.e. crosslinked) and subsequently dried under slight pressure to form collagen foam for dressings. See McKnight, Col. 3, lines 43-68 and Col. 4, lines 1-59. The gelling and crosslinking of the collagen fiber sets the film into a structured form and causes the protein and solvent to lose its mobile capabilities, thereby preventing the material to form an electromatrix material upon compression. Therefore, McKnight does not disclose or suggest an electromatrix material that is formed by compressing a properly prepared *intermediate material*, the non-brittle cohesive body. Hence McKnight does not disclose or suggest the electromatrix material of the claimed invention.

As explained in the previous paragraphs the protein matrix material of the claimed invention is derived from an intermediate material, the non-brittle cohesive body, that is formed prior to compression and which is not disclosed in McKnight. The collagen fiber dispersion disclosed or suggested in McKnight is gelled and subsequently crosslinked prior to compression, thereby not allowing compression to produce additional binding among the protein and solvent molecules as found when compressing a non-brittle cohesive body. Therefore, McKnight fails to disclose or suggest all the limitations of the claims of the present application. Since the limitations of the present claims are not found in the teaching of the collagen material disclosed by McKnight, Applicant respectfully requests that the rejection under 102(b) be withdrawn and that the pending claims be allowed.